

Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

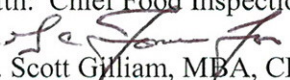


Indiana State Department of Health

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DATE: July 17, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: 
A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Luv N Care LTD Recall

**SUGGESTED
ACTION:** Unclassified Recall; all Nuby Gel Filled Teethers; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. Products were distributed through retail outlets nationwide and has been found to be marketed on the internet. The products are packaged in a plastic bubble on a printed card and can be identified by the UPC Codes. These products have been found to contain *Bacillus subtilis* and *Bacillus circulans* in the gel. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Luv N' Care, LTD Issues a Nationwide Recall of all Nuby Gel Filled Teethers and certain UPC Codes of Cottontails and Playschool Teethers

Contact:
Joseph H. Hakim

Luv N' Care, LTD
1-800-256-2399

FOR IMMEDIATE RELEASE - July 17, 2009 - Luv N' Care, LTD, Monroe, LA, is initiating a nationwide recall of all Nuby Gel Filled Teethers. These products have been found to contain *Bacillus subtilis* and *Bacillus circulans* in the gel. These bacteria generally do not cause illness. However, the bacteria can affect children with weakened immune systems, causing stomach pain, vomiting, and diarrhea, if the teether is punctured and the liquid from the teether is ingested.

Consumers who have Nuby Gel Filled Teethers and Cottontails and Playschool Teethers with any of the UPC Codes listed below should immediately stop using them, discard them or return them to the place of purchase for a full refund.

The recall includes the following products:

UPC code Brand Name

48526-00451 Nuby

48526-00452 Nuby

48526-00453 Nuby

48526-00454 Nuby

48526-00455 Nuby

48526-00459 Nuby

48526-00467 Nuby

48526-00472 Nuby

48526-00473 Nuby

48526-00482 Nuby

48526-00483 Nuby

48526-00487 Nuby

48526-00490 Nuby

48526-00519 Nuby

48526-00521 Nuby

41520-87115 Cottontails

50428-91511 Playschool

41520-91660 Cottontails

The firm voluntarily recalled the products after learning that samples of two lots collected by the Food and Drug Administration were found to contain *Bacillus subtilis* and *Bacillus circulans*, respectively in the gel. FDA has been apprised of this action.

No illnesses have been reported to date.

Product was distributed through retail outlets nationwide and has been found to be marketed on the internet. The products are packaged in a plastic bubble on a printed card and can be identified by the UPC Codes listed above.

The company has ceased product and distribution of the products and is notifying its distributors to return the product. Consumers are urged to return the product to the place of purchase for a full refund.

Consumers with questions may contact the company at 1-800-256-2399 ext. 3106 between 8:00 AM and 5:00 PM Central time.

Adverse reactions experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at:
www.fda.gov/MedWatch/getforms.htm.
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

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